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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,340	11/23/1999	Graca Raposo	255/013-US	8331

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LYON & LYON LLP
633 WEST FIFTH STREET
SUITE 4700
LOS ANGELES, CA 90071

EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 11/21/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,340

Applicant(s)

Raposo et al.

Examiner

G. R. Ewoldt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 31, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-19 is/are pending in the application.
- 4a) Of the above, claim(s) 2, 3, 6, 8-15, and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-15 and 17-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

1. Applicant's election of Group II, claims 1, 3-5, and 7, with traverse, in Paper No. 9, filed 9/07/01, is acknowledged. The traversal is on the grounds that the invention must be considered under unity of invention rules and that the standard for unity of invention states that the special technical features which define the instant invention must be considered as a whole, and further, that focusing on the lactadherin protein fails to consider said invention as a whole.

These argument are not found persuasive for the following reasons. One method of establishing a lack of unity is the citation of a prior art reference teaching the invention of an independent claim. In the instant case, U.S. Patent No. 5,455,031 teaches the product of Claim 6.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2-3, 6, 8-15, and 17-19 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Note that Claim 3, which depends on non-elected Claim 2 (and thus, is properly part of Group I), was inadvertently included in Group II. Claim 3 has been withdrawn as being drawn to nonelected invention.

Claims 1, 4-5, and 7 are being acted upon.

3. Claims 1, 4-5, and 7 are objected to for the recitation of "the mammal" and "the lactadherin". Proper claim language would be "said mammal" and "said lactadherin".

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 4-5, and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that Applicant was in possession of "variants" of lactadherin.

The specification defines the term "variant" of lactadherin as "an artificial protein, i.e., a protein artificially created, and not found in nature." Said definition comprises an insufficient description of the claimed invention as said definition would encompass essentially any mutated, substituted, deleted, or rearranged protein. It is further noted that the claimed "variant" need not even possess lactadherin biological function; said "variants" only "generally retain" biological function. Given the lack of a specific definition of the term, one of skill in the art would conclude that the specification fails to adequately describe the claimed invention. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 4-5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,505,955 (1996).

The '955 patent teaches a method of regulating an immune response in a mammal, including humans, comprising administering to the mammal a lactadherin. Said method further comprising the stimulation of phagocytosis of antigens by dendritic cells and the stimulation of cross-priming of antigens (see particularly column 3, lines 40-67 and column 7, lines 58-60). Note that lactadherin appears to be referred to in the art by several names including MFG-E8, BA46, and 46 Kd MW HMFG glycoprotein (as in the '955 patent). All these proteins are heavily glycosylated mucin-type proteins commonly found in milk.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ

430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Further note that while the reference does not specifically teach the stimulation of dendritic cells, said stimulation is an inherent property of the method taught by the reference.

The reference clearly anticipates the claimed invention.

8. Claims 1, 4-5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO95/15171 (1995).

WO95/15171 teaches a method of regulating an immune response in a mammal, including humans, comprising administering to the mammal a lactadherin or a variant thereof. Said method further comprising the stimulation of phagocytosis of antigens by dendritic cells and the stimulation of cross-priming of antigens (see particularly page 3, lines 30-35 and page 22, lines 10-16). Note that while the reference does not specifically teach the stimulation of dendritic cells, said stimulation is an inherent property of the method taught by the reference.

The reference clearly anticipates the claimed invention.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
November 19, 2001



Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600